

# SPL Process ER/DL Meeting

## Meeting Minutes

### Feb 10, 2016

**Chair of today's meeting:** Pat Cowall

Teleconference information:

USA Toll-Free: 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

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1. FEI numbers -- any updates since last meeting?

Nothing new. Herb shared his experiences, including a suggestion from FDA to change FEI numbers.

1/14/2016 meeting: Topic Anyone else getting requests to change what FEI number you are using? Somehow a number of our sites got multiple FEI numbers attached to them (before my time so I can only guess how that happened). We thought we had contacted the correct groups to have them merge the information and specify which number to use, but recently the FDA is coming back and telling us that we are using the wrong ones

Meeting Discussion:

- Sanofi: had the same request, but they negotiated back. They brought up original documentation. They were able to reinstate 3 out of 4 numbers. The number that didn't change was related to a number that was used in the inspection report.
  - They will send the details of who they worked with.
- Merck: had a request but they responded back. Timing was early December.
  - CDERcollections@fda.hhs.gov (Cheryl H. ) – their GDUFA establishment had an incorrect FEI numbers. The one that they wanted to use was on previous inspection reports. They wanted to change to the original number.
- Connie (Medimmune, astrazeneca): same situation – it was easier to just change to what FDA wanted.
- Who did you contact to correct this: eDRLS office and then forwarded to the ORA office.
  - Irma Rivera and Susan Laska
- All sites with new numbers were international.
- Terry:
  - We can bring this up at the leadership team. Is there a new process in place? Where did the different numbers come from? Did they have a migration from paper to electronic?
- Learning points:

- Make sure the manufacturing sites review the inspection reports to assure that the FEI number is consistent with the DER site.

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2. Is the address information that would be found on the artwork required to match the address information of the legal entity that the Labeler Code is attached to. If so, can someone tell me the regulation that says that. (Ben Harpster)

Meeting discussion:

- Uses corporate labeler code, with completely different address –
- Check 21 CFR 201.1 about name and address that you can use on the label.
  - See attachment
- Check 3 (g) – using the corporate address.

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3. How to drug list a co-packaged product. The co-packaged product is a kit and assigned it's own NDC Code. (Herb O'brien)

Herb can provided copy of the SPL.

New product code.

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4. SPL files with the marketing category "Approved Drug Product Manufactured Exclusively for Private Label Distributor" are submitted to the OC but are not publicly posted to Daily Med. How does the Orange Book get updated for private labels? (Herb)
  - This category is used only by manufacturing sites, who have to do their own drug listing. The PLD drug lists the finished product.
  - Drug for further processing: Per meeting minutes from Aug 2015:  
Document type being created for "Drug for further processing" (Lonnie)
    - a. Why? People are getting confused when they see the document type of "Bulk ingredient" - -- for products that use the marketing type of "Drug for further processing" – ie repackaging.
    - b. This new document type will be created soon. Specifically
      - i. Document type = Drug for further processing
      - ii. Marketing category = Drug for further processing
    - c. APIs should continue to use the
      - i. document type of "Bulk ingredient".
      - ii. Marketing category should be "bulk ingredient".
      - iii. No other inactive ingredients.
    - d. Will keep document type of "bulk ingredient" for bulk ingredients.
  - Orange Book –is a different type of contact with FDA. Drug listing does not get this into Orange Book.

- What is the Orange Book: Currently approved products - Rx and generics, CDER products. No biologics or OTC. Also patent information and therapeutic equivalency  
<http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>  
<http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm>
- Purple book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411424.htm>

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#### 5. Bulk ingredient vs drug for further processing. (Mary Knoll)

- What Marketing Category is everyone using?
- How are people handling bulk DL's?
- Are they checking with EDRLS that they have been accepted?

Bulk ingredient should use = API

Bulk drug product should use = Drug for further processing

You will get a second acknowledgement as verification that file was posted

What is timeframe for implementation: Current IG has these rules.

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#### 6. Leadership team updates:

- Indexing SPL files [Indexing – **Warning Letter SPL document**] will be produced with a link to the CDER Warning Letters posted on the FDA website. The reference is already included in the Implementation Guide and Validation Rules version out on the FDA website. No new data elements included in the indexing file. Expected roll-out of the new document type : February 2016. The files will be sent to the DailyMed group at NLM. In the future, [labels@fda.gov](mailto:labels@fda.gov) will have some functionality involving these new indexing files.
  - Sponsors will not have to do anything to their drug listing files.
  - FDA will create the SPL file and it will have a link to the actual warning letter.
  - Intent is to send these to NLM to be part of the Daily Med site
  - Intent is to make warning letters obvious to downstream users.
  - Later on, FDA is planning to have similar functionality on their labeling site.
- **Business Operation Qualifiers:** Human drug establishment vs Animal drug establishment. FDA is discussing the requiring inclusion of business operation qualifiers for Animal establishments, to more consistently identify whether an establishment is for animal or human drug.

Charisse Kasser

- Making these mandatory because this is useful for inspection purposes – to know what they are inspecting.
  - Pharma quality people sent out an email – “you are registered but we don’t see any drug listings”. Animal companies got this email too and wondered why they got the email. The qualifier will help identify.
  - Implementation will probably be in Q4 2016 when establishments do their next DER. It might get turned on earlier at time of FDA system update – for updates.
- **Package Marketing Start Date** – discussion about requesting that companies include this field. For SPL Products that are publicly available, data is available in the Comprehensive NDC SPL Data Elements (NSDE) At present, package marketing start date being derived from the submission date for products. With some companies submitting SPL files long after a product is first marketed, and variability in package marketing start dates. Having the package marketing start date included in the data from the companies will generally be more accurate than the derived date (from the submission date).

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#### 7. Updates to the IG: summary

##### Themes of Changes:

- New ISO country codes
- Active ingredient unii’s should be the same for all related nda, anda, bla. LOTS OF ERRORS BECAUSE OF INCONSISTENCIES
- Multiple change for - drug for further processing
- Multiple change for - Compounded and Animal compounded
- Multiple change for - Wholesale distributors
- New rules about contents of SPL
  - In Human Drug, then need 1 other COL section
  - Cartons/labels has to be last section.
- Lot Distribution: do not put in any leading zeroes before the first digit of the labeler code in the OID.

##### NEW:

- Drug substance Indexing SPL – regulation is coming. FDA is creating this File
- Index warning letter alerts – guidance coming

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#### 8. Establishment registration – Importers: Tiffany Chamberlain:

- Always indicate the physical location of the importer.

- Do you always use the warehouse? Or the company being sold to?
  - i. The include everyone in the DER who is involved – warehouse, broker who handles it, and company actually purchasing the product.
  - ii. This has helped with the import process.
  - iii. Also used in the shipping document.

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